



International Warehouse Logistics Association

July 3, 2000

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857

Re: Docket Nos. 92N-0297 and 88N-0258

Dear Sir or Madam:

On behalf of the International Warehouse Logistics Association (IWLA), I am writing to comment on the rule referenced above.

IWLA members are owners of public warehouses. The function of a public warehouse is defined in Article 7 of the Uniform Commercial Code (U.C.C.). This section contains the law governing the transactions between a warehouseman and its customer. It is the law in 49 of the 50 states, Louisiana having adopted variations.

In Article 7.102(1)(h) of the U.C.C., warehouseman is defined as a "person engaged in the business of storing goods for hire." Another definitional aspect of warehouse law, is one which recognizes that a "warehouseman" is one who has care, custody and control of the goods of another. Luther Transfer & Storage, Inc. v. Walton, 156 Tex. 492, 296 S.W. 2d 750 (1957) and Merritt v. Nationwide Warehouse Co., 605 S.W. 2d 250 (Tenn. 1980).

With respect to the Prescription Drug Marketing Act (PDMA), a public warehouse is not a "wholesale distributor" of prescription drugs. The public warehouse neither has title to the product nor exercises independent judgement over the product. A public warehouse is not involved in the sale, trade, donation, or the offer to sell, trade, or donate prescription drugs.

In 1993, the Food and Drug Administration confirmed that public warehouses are not considered to be wholesale distributors under the Prescription Drug Marketing Act amendments to the Federal Food, Drug, and Cosmetic Act. In an April 27, 1993, letter to the American Warehouse Association, now known as the International Warehouse Logistics Association, the FDA said:

"Accordingly, public warehouses (i.e., a warehouse that only provides space and/or labor for the storage of goods for hire) are not considered by the Agency

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to be 'wholesale distributors' when they are not involved in the sale, trade, donation, or the offer to sell, trade, or donate prescription drugs. However, those wholesale distributors who utilize a public warehouse to store prescription drugs must ensure that the public warehouse meets the storage, handling, and recordkeeping requirements of 21 CFR 205.50."

Since the receipt of the 1993 letter, there continue to be instances where a public warehouse has been wrongly identified as a wholesaler by state agencies, manufacturers, or wholesalers.

The final PDMA's regulation issued by the FDA in December 1999 are cause for further concern by public warehouses. There is need for a modification to the regulatory text of §203.50 to clearly state that the provisions of this section are not applicable to a public warehouse because a public is **not** a wholesale distributor for purposes of the PDMA.

This modification would be consistent with the Agency's April 27, 1993, letter. Without this modification, a public warehouse could be wrongfully referred to as either an "authorized distributor" or an "unauthorized distributor." Neither term is correct, as a public warehouse is not a wholesaler distributor in any sense of the word.

The need for the modification is underscored by §203.50(d), which requires a manufacturer to "maintain a current written list of all authorized distributors of record", and to "make its list of authorized distributors of record available on request to the public for inspection or copying." These requirements confer on the manufacturer the ability to unilaterally determine that a public warehouse is a wholesale distributor and subject to the requirements for an "authorized distributor." Further, if Manufacturer A lists a warehouse but Manufacturer (B) does not, it may wrongfully be interpreted that the public warehouse is an "unauthorized distributor" of Manufacturer B and thus subject to the requirements for an "unauthorized distributor." Yet, in reality, the public warehouse is neither an "authorized" or "unauthorized" distributor. Stating this in the rule will eliminate a potentially burdensome and confusing problem.

Thank you for your consideration.

Sincerely,

Joel Hoiland
President and CEO